Informed Consent Issues in MIRIAD

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The Challenges of Informed Consent in MIRIAD

- **Substantial proportion of women recruited in labor (peripartum group 70%)**

Women enrolled intrapartum may represent particularly vulnerable group

- Pregnant women with no prior prenatal care
- No established relationship with provider or health care system
- Labor physically and emotionally demanding
- Focus of woman on anticipated delivery, alleviation of pain
- Circumstances of labor amplify difficulties of pretest/posttest HIV counseling
- Includes recent immigrants, non-English speakers, poor women, women of color

Major Aims of MIRIAD

- To determine the feasibility and acceptance of informed consent for rapid testing
- To evaluate the informed consent process in order to develop a more effective and efficient method for approaching women in labor and delivery

How to address intrapartum informed consent issues in context of MIRIAD

- Small focus groups
- Development of flip-charts
- Pilot of process
- On-going evaluation of process

Preliminary Focus Groups

- Women may wish to defer receipt of test result until after delivery
- Checkboxes added to informed consent form allowing women to be tested and treated in labor; receive results and post-test counseling after delivery

I want to participate in MIRIAD

No

Yes

If you answered “yes above, please fill out the next 2 questions.

I want to be told the rapid test result as soon as possible, even during labor or delivery.

Yes

No, I **do not** want to be told the rapid HIV test result until **after I give birth**

If my rapid test result is positive, I want medicine right away to help prevent HIV in the baby.

Yes, medicine for me in labor and to my baby.

Yes, medicine for me only

Yes, medicine for my baby only

No, I do not want medicine and do not want my baby to get medicine

Development of flip charts to supplement informed consent process

- Outside consultant with expertise in flip-chart development
- Pictures with accompanying text
- Piloted with separate groups of HIV-infected and HIV-uninfected focus groups in 3 cities (Atlanta, Chicago, Miami)
- Simpler, fewer pictures, wanted text, liked “universal” woman, more words rather than fewer in bullets

Pilot Study

- "Mock" informed consent process
- Series of open-ended questions
- Subjective reaction to process
- Conducted at 3/5 MIRIAD sites (Miami, New Orleans, Chicago)
- Women in labor with known HIV status asked to participate

Characteristics of and results from 28 women who participated in informed consent pilot study

HIV-infected	9 (32%)
Substantial pain	17 (61%)
Less than 15 minutes to complete interview	16 (57%)
One or more interruptions during interview	20 (71%)
Able to correctly state in their own words	
Purpose	20 (71%)
Benefits	19 (68%)
Risks	7 (25%)
Stated that there were no risks associated with study	12 (43%)
Understood right to withdrawal from study at any time	20 (71%)

Intrapartum Consent Process (based on pilot and preliminary information)

- Presentation of flip-chart
- Ask 4 open-ended questions (Purpose, risks, benefits, withdrawal) and score recorded
- Wrong answers reviewed and rehearsed until correctly answered
- Read and sign informed consent form

Postpartum Evaluation

- Postpartum interview (3 HIV-uninfected: 1 HIV-infected), ask same 4 open-ended questions and score recorded
- Women declining rapid testing also offered postpartum interview
- Additional questions – reasons for declining/accepting testing, how strongly providers recommended testing

Summary

- Challenges of offering rapid HIV C&T in labor to particularly vulnerable group at particularly vulnerable time
- Major aim of MIRIAD to find out how to best approach these women